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## 510(k) SUMMARY

APR - 4 2008

**Date Prepared:** January/09/2008

**Submitter:** Zimmer Medizinsysteme GmbH  
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Germany  
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**Device Trade Name:** CryoMini

**Common Name:** Skin Refrigerant

**Classification:** Class II (21CFR 878.4810)  
Laser surgery instrument for use in general and plastic surgery and dermatology.

**Performance Standards:** None established (as a medical device) under section 514.

**Description of Device:** The CryoMini consists of a refrigeration unit that creates cold air. The cold air is blown onto the skin using an air hose. The details of CryoMini are described in section 7 "Device Description and Comparison.doc".

**Intended use of the Device:** The CryoMini Cold Air Device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

**Substantial Equivalence Claim to the following legally marketed devices:**

1. Cryo V6.0 (Zimmer) K060395

**Summary of Substantial Equivalence:**

Compared with already cleared device Cryo V6.0, at CryoMini mechanical dimensions and placement on the electronic board changed. The smaller device size is well tested and proofed by reasonable people. Also the electronic safety test and functionality is tested and verified.

Equal to Cryo V6.0 mechanical and electrical safety of Cryo V6.0 are tested against the standards UL60601-1 and IEC60601-1-2.

The effectiveness is tested by an air flow measurement at Zimmer Medizinsysteme GmbH. The measurement shows that the maximum output air flow of CryoMini is higher than air flow of Cryo V6.0 but also the minimum air temperature is higher than in Cryo V6.0. Some more tests show that similar to Cryo V6.0 the necessary therapy skin temperature is reached with CryoMini also.

The Zimmer CryoMini is substantially equivalent to the compared device on the basis of similarities in operating principles, intended use and functional performance.

**Summary of fundamental technology:**

The modifications have not altered the fundamental technology of predicate device the Cryo V6.0.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 4 2008

Zimmer Elektromedizin GmbH  
% TÜV SÜD Product Service GmbH  
Stefan Preiss  
1775 Old Highway 8 NW  
New Brighton, Minnesota 55112

Re: K080735

Trade/Device Name: CryoMini, Skin Refrigerant  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and  
in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: March 26, 2008  
Received: March 28, 2008

Dear Stefan Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

d. Intended Use

Device Name: CryoMini, Skin Refrigerant

Indications for Use: The CryoMini Cold Air Device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ozkan for name  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K080735